REMARKS

Claims 1 and 2 are now pending in this application.

Claim 1 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 1 has been amended to clarify issues raised by the Examiner, and claim 2 has been added.

Claim 1 stands rejected under 35 U.S.C. 103(a) and being unpatentable over BD Bioscience. This rejection is respectfully traversed.

In intravascular hemolytic anemia, the presence of fragmented red blood cells in the peripheral blood is the most important sign. However, the only available method to confirm the presence of fragmented red blood cells and to monitor their amount is the microscopic examination of blood smears. This method is a labor intensive and time-consuming process, and distinguishing fragmented red blood cells from indented normal red blood cells is often difficult. Therefore, an improved diagnostic test of hemolytic anemia is needed. Here, we introduce a new, sensitive and accurate diagnostic method for hemolytic anemia by flow cytometry using an anti-hemoglobin antibody which detects fragmented red blood cells. The fragmented red blood cells are stained with the anti-hemoglobin antibody in hypotonic solution, 0.6% NaCl, and not in isotonic solution. The present invention is the first method of diagnosing hemolytic anemia, especially fragmented red blood cells, using anti-hemoglobin antibody by an instrument, flow cytometer.

This method of the present invention is very different from that of BD Biosciences (Technical Resources 2000, page 176). The following are the different points.

1. The method of BD Biosciences deal with nucleated cells (white blood cells not red blood cells) and all red blood cells are lysed using lysing solution before staining the target nucleated cells (page 176, Lysing and Staining No. 3). BD Biosciences has never described any method dealing with red blood cells. In contrast, in applicant's claimed method the red blood cells are the target cells. Consequently, red blood cells should not be lysed as in the method of BD Biosciences. Therefore, these two methods are different from the beginning.
2. In the method of BD Biosciences, the cells are stained in isotonic solution. BD Biosciences does not contemplate any staining method in hypotonic solution. But in applicant's method, the red blood cells should be stained in hypotonic solution. If you stain red blood cells in isotonic solution, you cannot get a positive result. Therefore, the major differences between applicant's claimed method and that of BD Biosciences are with or without lysing red blood cells and in isotonic or hypotonic solution. Another point is using an anti-hemoglobin antibody for making diagnosis of hemolytic anemia.

Accordingly, in view of the above amendments and remarks, reconsideration of the rejection and allowance of all of the claims of the present application are respectfully requested.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mr. Joseph A. Kolasch (Reg. No. 22,463) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. 1.17 and 1.136(a), the Applicant respectfully petitions for a one (1) month extension of time for filing a response in connection with the present application and the required fee of $110.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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